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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/306,006	05/06/99	SUPERSAXO	A NB/2-21551/A

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EXAMINER

SHARAREH, S

ART UNIT**PAPER NUMBER**

1619

DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/306,006

Applicant(s)

SUPERSAXO ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/18/01, 3/22/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,6,10,15-21,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,6,10,15-21,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Continued Prosecution Application

The request filed on April 18, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/306,006 is acceptable and a CPA has been established. An action on the CPA follows.

Status of the Claims

The Amendment after final filed on May 22, 2001 has been entered. Claims 2, 6, 10, 15-21, 28-29 are now pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 6, 10, 15-21, 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of step (c) in claims 28-29 is vague. It is not clear what is meant by the phrase "in which any pharmaceutically active agent is lipophilic and is always present as component (c)".

In claims 6, and 10, the recitation of the phrase "methodwhich is characterized in that the nanodispersion comprises" renders the claim ambiguous. It is not clear how is the method characterized in using a nanodispersion comprising a phospholipid. The use of standard transitional phrase in the language of claims is recommended. (see MPEP 2111.03)

Further, the language of claim 10 appears to be in improper Markush language. It is not clear if the component (b) requires all of the recited moieties or only one. Accordingly, the metes and bounds of the claim are not clear. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925).

Claim 15 recites the limitation "the pharmaceutical end formulation" in line 2 of the claim. It is not clear to which pharmaceutical end formulation is applicant referring. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 6, 10, 15-21, 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Weder et al WO 96/37192 ('192).

The instant claims are aqueous nanodispersion formulations consisting essentially of (a) 0.1-30% by weight of phospholipid (b) 1-50% by weight of polyoxyethylene coemulsifier (c) 0.1-80% by weight of loop-hole component which is a natural or synthetic C 4- C 18 triglyceride and a lipophilic active agent, (d) 0.63-14.2%

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by weight ethanol and water phase. The claims are also directed to methods of preparing said nanodispersion formulations.

Applicant is also informed that claim 16-19 are drafted as "product-by-process" claims. Accordingly, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113). "Even though product - by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe , 227 USPQ 964, 966 (Fed. Cir. 1985).

'192 patent disclose compositions having nanoparticles in 10-15 nm range comprising a, phospholipid, a polyoxyethylene coemulsifier, a triglyceride, an active drug, and ethanol as a solvent. The instant claims are also directed to methods of preparing such compositions (see examples 1-4, pages 22-25). '192 clearly disclose the use of all elements of the instant compositions (pages 6-17, 27, claim 3).

With respect to the method claims, Examiner states that the policy of the US PTO is to give pending claims their broadest reasonable interpretation. The instant open-ended claims comprise and do not exclude any components essential to the operability of the cited prior art patents. In the instant case, the recitation of "step (β) is carried out ^{in the} absence of high shear or cavitations forces" is given its broadest reasonable interpretation. Accordingly, consistent with the method steps recited in the instant

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specification, '192 discloses mixing the individual components of its compositions at room temperature with a magnetic stirrer at about 500-1000rpm (see examples 1-4)

Thus, '192 meets such limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 6, 10, 15-21, 28-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Weder US Patent 5,997,888⁵⁵ in view of WO 96/37192 ('192).

The instant claims are aqueous nanodispersion formulations consisting essentially of (a) 0.1-30% by weight of phospholipid (b) 1-50% by weight of polyoxyethylene coemulsifier (c) 0.1-80% by weight of loopole component which is a

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natural or synthetic C 4- C 18 triglyceride and a lipophilic active agent, (d) 0.63-14.2% by weight ethanol and water phase. The claims are also directed to methods of preparing said nanodispersion formulations.

Weder et al disclose cosmetic compositions contacting nanodispersions comprising a fatty acid esters of polyoxyethylene sorbitans as emulsifying agent in amount of 0.1%-5%, at least one phospholipid in amount of 0.1%-5%, ethanol in amount of 0.65%, a water phase and a lipophilic active agent such as tocopherol acetate, or vitamin A palmitate (examples 1-5, claims 1-10). Weder also teach conventional mixing of their components using a magnetic stirrer or a static mixer (col 8, lines 1-5). Weder further discloses that their mean particle size is about 50 nanometers (col 8, lines 14-18). Weder et al however fail to specifically use a combination of triglycerides and the active lipophilic agent.

'192 patent is discussed above. '192 teaches the instant claimed compositions, nevertheless, it is simply used to show that the use of triglycerides to improve stability and solubility of lipophilic drug in an aqueous emulsion system is conventional. (see entire document, claims 1-5).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to further incorporate a triglyceride moiety with the lipophilic active agent of Weder, as taught in '192 patent, because he would have had a reasonable expectation to succeed in improving the stability and thus shelf half life of the nanodispersions of Weder. Furthermore, methods of incorporating triglycerides into

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Weder's compositions would have also been routine and well within purview of an ordinary artisan.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 6, 10, 15-21, 28-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-45 of copending Application No. 09/306,005. Although the conflicting claims

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are not identical, they are not patentably distinct from each other because they are substantially directed to similar compositions and methods of preparing thereof.


This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.


DIANA DUDASH
SUPERVISORY PATENT EXAMINER
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